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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/995,022 | 11/26/2001 | Holger G. Gassner | 07039-171002 | 1634 |

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| EXAMINER | |
|---|---|
| JAGOE, DONNA A | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1614 | |

DATE MAILED: 01/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/995,022 | GASSNER ET AL. | |
| | Examiner | Art Unit | |
| | Donna Jagoe | 1614 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *16 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *23 and 32-46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *23 and 32-46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

## DETAILED ACTION

***Claims 23 and 32-46 are presented for examination.***

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 23, 32-33, 35, 37-40 and 42 are rejected under 35 U.S.C. 102(b) as being anticipated by Sanders et al. U.S. Patent No. 5,766,605 A.

The claims are drawn to an article of manufacture comprising an admixture of botulinum toxin, a local anesthetic such as lidocaine and a vasoconstrictor.

Sanders et al. teach a composition comprising the decongestant neosynephrine® (phenylephrine, a vasoconstrictor), xylocaine® spray (lidocaine) and type A botulinum toxin. All ingredients were administered to the right and left nasal cavities of anesthetized dogs (column 8, lines 21-36).

There does not appear to be any unexpected results when the composition of botulinum toxin, local anesthetic and vasoconstrictive agent is admixed in a container immediately prior to use. Page 16 of the instant specification recites that the effects of the BoTox® induced muscle paralysis faded in a symmetric fashion referring to a subject injected with lyophilized botulinum toxin reconstituted with saline in one area of the forehead and lyophilized botulinum toxin reconstituted with lidocaine with epinephrine

on the other side of the forehead. Applicant's argument made in the interview dated July 9, 2003, wherein it the non-obviousness of admixing a substance with a pH of less than 5 (lidocaine with epinephrine) with a protein was discussed. Applicant argues that one would expect the protein to denature or not be stable. However, this information does not appear in the instant specification and cannot be relied upon for patentability.

Applicants assert that the sequential administration of a botulinum toxin, a local anesthetic and a local vasoconstrictive agent to treat vasomotor rhinitis does not teach or suggest an article of manufacture comprising an admixture of the three components having packaging material and/or a label directed to treatment of skin wounds as presently recited. In response to applicant's argument, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). In response to applicant's arguments, the recitation of "a label directed to treatment of skin wounds" has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 23 and 32-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adams et al. U.S. Patent No. 4,029,794, in view of Sanders et al. U.S. Patent No. 5,766,605 A.

Claims 23 and 32-36 are drawn to an article of manufacture comprising botulinum toxin, a vasoconstrictor such as epinephrine and a local anesthetic such as lidocaine;

Claims 37-41 are drawn to an article of manufacture comprising botulinum toxin, a local anesthetic with a further dependent claim drawn to a vasoconstrictor such as epinephrine;

Claims 42-43 are drawn to an article of manufacture comprising botulinum toxin and a vasoconstrictor.

Claims 44-46 are drawn to the article of manufacture further comprising packaging material and labels to direct the user.

1. Adams et al. teach a toxin such as saxitoxin (see abstract) along with local anesthetics such as lidocaine (see examples, column 2, line 40 to column 4, line 60, see also table A). In addition, vasoconstrictors may be added for administration by infiltration or injection (column 5, line 67 to column 6, line 48).

2. Sanders et al. teach a composition comprising the decongestant Neosynephrine® (phenylephrine, a vasoconstrictor), xylocaine® spray (lidocaine) and type A botulinum toxin. All ingredients were administered to the right and left nasal cavities of anesthetized dogs (column 8, lines 21-36).

1. Adams et al. does not teach botulinum toxin

2. Sanders et al. does not teach the vasoconstrictor epinephrine

1. Regarding the neurotoxin saxitoxin, to substitute the neurotoxin botulinum toxin for the neurotoxin saxitoxin would have been obvious. It is prima facie obvious to substitute equivalents, motivated by the reasonable expectation that the respective species will behave in a comparable manner or give comparable results in comparable circumstances as noted in Sanders et al above. *In re Ruff* 118 USPQ 343; *In re Jezel* 158 USPQ 99; the express suggestion to substitute one equivalent for another need not be present to render the substitution obvious. *In re Font*, 213 USPQ 532.

2. Regarding the vasoconstrictor, phenylephrine, of Sanders et al, to substitute the vasoconstrictor epinephrine for the vasoconstrictor phenylephrine would have been obvious. It is prima facie obvious to substitute equivalents, motivated by the reasonable expectation that the respective species will behave in a comparable manner or give comparable results in comparable circumstances. *In re Ruff* 118 USPQ 343; *In re Jezel* 158 USPQ 99; the express suggestion to substitute one equivalent for another need not be present to render the substitution obvious. *In re Font*, 213 USPQ 532.

Regarding the packaging material and label, it is a standard of practice in the pharmaceutical arts to enclose a composition in a vessel, and to enclose instructions for use in a package. It appears that applicant is attempting to claim a kit since it appears that the lyophilized botulinum toxin is mixed with the lidocaine or lidocaine with epinephrine, immediately prior to use, whereupon it would not be an admixture until the contents of both vessels are mixed.

***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna Jagoe whose telephone number is (703) 306-5826. The examiner can normally be reached on Monday through Friday from 8:00 A.M. - 4:30 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3230.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Donna Jagoe
Patent Examiner
Art Unit 1614

Frederick Krass
Primary Examiner
Art Unit 1614